



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,849	01/30/2002	Stephen Mark McAllister	P51223	9605

7590 01/27/2011
GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

01/27/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/060,849	Applicant(s) MCALLISTER ET AL.	
	Examiner S. TRAN	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/10 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that the specification does not provide support for the following limitations:

1) The "first and second dissolution modifying excipient". This limitation requires that certain excipients (disintegrant, surfactant, and swellable solid) be the first

Art Unit: 1615

excipients, and certain excipients be the second excipients. See for example claims 11, 12 and 14. In another word, the limitation basically precludes certain combination of certain groups of excipients. This does not appear to be adequately support by the present specification which discloses combinations of any excipients;

2) "the capsule shell upon being exposed to a gastro-intestinal environment dissolves in a time/controlled release dependent manner"; and

3) The limitations of claims 144 and 145.

In accordance with MPEP § 714.02, applicant should specifically point out support for any amendment made to the disclosure.

Claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: 1) breadth of the claims, 2) nature of the invention, 3) state of the prior art, 4) amount of direction provided by the inventor, 5) the level of predictability in the art, 6) the existence of working examples, 7) quantity of experimentation needed to make or use the invention based on the content of the disclosure, and 8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors being discussed below:

Breadth of the claims: independent claims 1 and 73 are directed to a composition comprising a copolymer of methyl acrylate, methyl methacrylate and methacrylic acid, wherein the composition is substantially pH-independent.

State of the prior art: the prior art teaches that copolymer of methyl acrylate, methyl methacrylate and methacrylic acid is known to have pH-dependent property. See for example teachings in Chiao et al. (paragraph 0049), Heinicke (paragraph 0033), and He et al. (paragraph 0011). The present specification does not provide any adequate guidance for the limitation “substantially pH-independent”. According to the teachings in the prior arts, it is not understood how the claimed copolymer, which is known in the art as a pH-dependent polymer, is indeed, a pH-independent in the present case.

As such, the practitioner would turn to trial and error experimentation in order to compose a composition comprising a copolymer of methyl acrylate, methyl methacrylate and methacrylic acid, wherein the composition is substantially pH-independent, without guidance from the specification.

The quantity of experimentation: there is a substantial gap between a composition comprising the claimed copolymer, and one comprising the same copolymer but obtain different properties. As stated earlier, the prior arts teach that copolymer of methyl acrylate, methyl methacrylate and methacrylic acid is pH-dependent. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

The relative skill of those in the art: the skill of those in the art is very high, *e.g.*, Ph.D. or M.D. level technology.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 73 are rejected in the use of improper Markush language. It is noted that line 20 of claim 1 and line 17 of claim 73 recite the word “or”, which if proper Markush language is used, should read “and”.

Claims 1 and 73 are rejected because it is not entirely clear whether items (a) through (d) in the claims are supposed to be altogether or in an alternative manner.

Claim 73 recites the limitation “the capsule shell” in third to last line. There is insufficient antecedent basis for this limitation in the claim.

Claims 18, 20, 24, 75, 81, 114, 121, 139 and 142 are rejected in view of the word “and” preceding the word “combinations” or “mixtures thereof”. It is not entirely clear whether all of the components recited in the claims are used together as a combination, a mixture, or individual. Clarification is requested.

Claim 147 is rejected for failing to further limit the subject matter of claim 73. Claim 73 recites lubricant in an amount of “10 to about 30%”, however, claim 147

Art Unit: 1615

recited lubricant in an amount of "about 10". The term "about" includes limitations below 10%, which is outside the range recited in claim 73.

Response to Arguments

Applicant's arguments filed 06/28/10 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606.

The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615